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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,778	06/11/2001	Minoru Ueda	UEDA 3	9769

1444 7590 06/05/2002

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/05/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,778

Applicant(s)

UEDA ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 9.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Interview Summary

Application No.

09/857,778

Applicant(s)

UEDA ET AL.

Examiner

BJ Forman

Art Unit

1634

All participants (applicant, applicant's representative, PTO personnel):

(1) BJ Forman. (3)_____.

(2) Asst. for Mr. Neimark. (4)_____.

Date of Interview: 17 May 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The examiner contacted Mr. Neimark's asst. to inform them that the IDS and 1449 filed on 13 Sept. 2001 was missing from the case and to requested a copy of the IDS and 1449. A copy of the original was provided by FAX and was put into the case. References listed on the 1449 were in the case.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Art Unit: 1634

DETAILED ACTION

Information Disclosure Statement

1. The references listed on the 1449 received 13 September 2001 (a copy of which was provided by FAX on 17 May 2002) have been reviewed and considered. Additionally, the International Search Report and the references cited therein have been considered.

Claim Objections

2. Claims 5, 7-10, 12 and 14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). For purposes of examination, the claims 5, 7-10, 12 and 14 have been interpreted as depending from Claim 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite for the recitation "stringent conditions" because "stringent" is a non-specific relative term which requires definition or criteria for determining. It is suggested that Claim 15 be amended to define or recite criteria for determining stringent conditions (page 21, lines 15-22).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-7, 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Guo et al (Nucleic Acids Research, 1994, 22(24): 5456-5465).

Regarding Claim 1, Guo et al disclose a method for immobilizing an oligonucleotide onto a support comprising spotting a buffer containing an oligonucleotide onto a support (page 5457, left column second full paragraph, lines 10-17) and immobilizing the oligonucleotide onto to support via a covalent bond (Abstract, lines 4-6).

Regarding Claim 2, Guo et al disclose the method wherein a functional group is introduced into the oligonucleotide i.e. amino group (page 5457, left column, first full paragraph, lines 3-6).

Art Unit: 1634

Regarding Claim 3, Guo et al disclose the method wherein the functional group is introduced at a terminus of the oligonucleotide i.e. 5' (page 5457, left column, first full paragraph, lines 3-6).

Regarding Claim 4, Guo et al disclose the method wherein an amino group is introduced into the oligonucleotide (page 5457, left column, first full paragraph, lines 3-6).

Regarding Claim 5, Guo et al disclose the method wherein the support has a functional group (page 5457, left column, second full paragraph, lines 1-8).

Regarding Claim 6, Guo et al disclose the method wherein the support has an aldehyde group (page 5457, left column, second full paragraph, lines 1-8, page 5458.Fig. 1 and page 5459, left column, first full paragraph).

Regarding Claim 7, Guo et al disclose the method wherein the oligonucleotide is immobilized onto the support through a spacer between the oligonucleotide and the surface of the support (page 5458.Fig. 1 and page 5459, left column, first full paragraph).

Regarding Claim 9, Guo et al disclose the method wherein the support is made from glass and is a treated surface of glass (page 5458, right column, last paragraph and Fig. 1).

Regarding Claim 10, Guo et al disclose the method wherein the buffer comprises a carbonate (page 5457, left column, second full paragraph, lines 10-15).

Regarding Claim 11, Guo et al disclose the method wherein the concentration of the carbonate is 10 to 500 m M (page 5457, left column, second full paragraph, lines 10-15).

Regarding Claim 12, Guo et al disclose a material onto which an oligonucleotide is immobilized prepared according to the method of claim 1 (page 5463, Fig. 4).

Regarding Claim 13, Guo et al disclose the material of Claim 12 wherein the oligonucleotide is immobilized at 1.25 fmole/dot or more (page 5463, Fig. 4).

Regarding Claim 14, Guo et al disclose a method for detecting a target nucleic acid comprising detecting a target nucleic acid by using the material onto which an oligonucleotide is immobilized as defined in Claims 12 or 13 (page 5458, left column, paragraphs 1-3).

Art Unit: 1634

Regarding Claim 15, Guo et al disclose the method of Claim 14 comprising hybridizing the material under stringent conditions (page 5460, left column, last paragraph). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein stringent conditions are not defined. Therefore, the hybridization conditions of Guo et al which produced consistent and reproducible results without interfering background is encompassed by the claimed stringent conditions. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

7. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothberg et al (U.S. Patent No. 6,355,423, filed 3 December 1997).

Regarding Claim 1, Rothberg et al disclose a method for immobilizing an oligonucleotide onto a support comprising spotting a buffer containing an oligonucleotide onto a support and immobilizing the oligonucleotide onto to support via a covalent bond (Column 81, line 45-Column 82, line 57).

Regarding Claim 2, Rothberg et al disclose the method wherein a functional group is introduced into the oligonucleotide i.e. amino group (Column 82, lines 24-31).

Regarding Claim 3, Rothberg et al disclose the method wherein the functional group is introduced at a terminus of the oligonucleotide (Column 82, lines 24-31).

Regarding Claim 4, Rothberg et al disclose the method wherein an amino group is introduced into the oligonucleotide (Column 82, lines 24-31).

Art Unit: 1634

Regarding Claim 5, Rothberg et al disclose the method wherein the support has a functional group (Column 53, lines 39-45).

Regarding Claim 6, Rothberg et al disclose the method wherein the support has an aldehyde group (Column 53, lines 39-45).

Regarding Claim 7, Rothberg et al disclose the method wherein the oligonucleotide is immobilized onto the support through a spacer between the oligonucleotide and the surface of the support (Column 55, lines 1-32).

Regarding Claim 8, Rothberg et al disclose the method wherein 200nl or less of the buffer containing 1 μ M oligonucleotide is spotted onto the support (Column 55, lines 47-64)

Regarding Claim 9, Rothberg et al disclose the method wherein the support is made from glass and is a treated surface of glass (Column 53, lines 39-45).

Regarding Claim 10, Rothberg et al disclose the method wherein the buffer comprises a carbonate (Column 55, lines 47-61).

Regarding Claim 11, Rothberg et al disclose the method wherein the concentration of the carbonate is 10 to 500 m M (Column 55, lines 51-52).

Regarding Claim 12, Rothberg et al disclose a material onto which an oligonucleotide is immobilized prepared according to the method of claim 1 (Column 83, line 54-Column 84, line 4).

Regarding Claim 13, Rothberg et al disclose the material of Claim 12 wherein the oligonucleotide is immobilized at 1.25 fmole/dot or more (Column 83, lines 35-38).

Regarding Claim 14, Rothberg et al disclose a method for detecting a target nucleic acid comprising detecting a target nucleic acid by using the material onto which an oligonucleotide is immobilized as defined in Claims 12 or 13 (Column 84, lines 6-36).

Regarding Claim 15, Rothberg et al disclose the method of Claim 14 comprising hybridizing the material under stringent conditions (Column 84, line 64-Column 84, line 20). The claims are given the broadest reasonable interpretation consistent with the indefinite claim

Art Unit: 1634

language and specification wherein stringent conditions are not defined. Therefore, the hybridization conditions of Rothberg et al from which hybridization efficiency was determined for various spacers is encompassed by the claimed stringent conditions. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al (Nucleic Acids Research; 1994, 22(24): 5456-5465) in view of Rothberg et al (U.S. Patent No. 6,355,423, filed 3 December 1997).

Regarding Claim 8, Guo et al teach the method for immobilizing an oligonucleotide onto a support comprising spotting a buffer containing an oligonucleotide onto a support (page 5457, left column second full paragraph, lines 10-17) and immobilizing the oligonucleotide onto to support via a covalent bond (Abstract, lines 4-6) wherein an oligonucleotide concentration of 1 μ M or more is spotted onto the support (page 5457, left column, second full paragraph, lines 10-15) but they do not teach buffer volume of 200nl or less. However, nl

Art Unit: 1634

buffer volumes were well known and routinely practiced in the art at the time the claimed invention was made as taught by Rothberg et al who teach that probe/buffer concentrations are altered to optimize hybridization results (Column 53, line 65-Column 54, line 14). Specifically, Rothberg et al teach a similar method for immobilizing an oligonucleotide comprising spotting a buffer containing an oligonucleotide onto a support and immobilizing via a covalent bond wherein 200nl or less of buffer containing oligonucleotide at 1 μ M or more is spotted onto the support (Column 81, line 45-Column 82, line 57). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe/buffer concentrations in the spotting method of Guo et al using routine experimentation as suggested by Rothberg et al to thereby optimize concentrations for the expected benefits of maximizing experimental results. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7- 9, 12, 31 and

Art Unit: 1634

32 of copending Application No. 09/857,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods for immobilizing oligonucleotides onto a support and differ only in the '773 claims being drawn to a species of oligonucleotides i.e. DNA. However, the courts have stated that a genus is obvious in view of the teaching of a species (see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989)). Therefore the instantly claimed genus (oligonucleotide) is obvious in view of the '733 claimed species (DNA).

12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
May 21, 2002